



**Department of Energy
Oak Ridge Operations
Office of Environmental Management
Procedure**



Integrated Assessment Program

**EM – 3.3
Revision 1**

Prepared: Andrew B. Perkins 2/18/2004
Procedure Owner Date:

Approved: JHM Crackman 3/2/04
Assistant Manager for Environmental Management Date:



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Approved:

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LIST OF ACRONYMS

AL	Assessment Lead
AMEM	Assistant Manager for Environmental Management
CA	Corrective Action
CAP	Corrective Action Plan
	Contractor
COR	Contracting Officer's Representative
DD	Division Director
DOE	U. S. Department of Energy
EM	Office of Environmental Management
FR	Facility Representative
IAS	Integrated Assessment Schedule
IVR	Independent Verification Review
ORION2	Oak Ridge Issues, Open Items, and Nonconformance Tracking System
ORO	Oak Ridge Operations Office
	Project Manager
	Quality Assurance
	Subject Matter Expert
TL	Team Lead
WL	Walkthrough Lead

1.0 PURPOSE

This procedure describes the roles, responsibilities, and basic processes to be used for the management of the ORO EM Integrated Assessment Program.

2.0 SCOPE

This procedure applies to all DOE Oak Ridge Operations (ORO) EM divisions, programs, and projects. It includes the following assessment elements:

- Schedule Development
- Walkthroughs and Corrective Actions of Contractor Operations
- Formalized Assessments and Corrective Actions of Contractor Operations (in accordance with DOE O 425.1 and EM Procedure 2.1)
- Safety Basis Changes and Implementation Verification
- Adequacy of contractor's Implementation Verification Review
- Assessment of Significant Safety Systems (in accordance with Phase II CRADs)
- Project Audits (in accordance with DOE O 413.1A)

This procedure supercedes the following ORO EM documents:

- EM-6.1 "Corrective Actions"
- EM-6.2 "Assessments"
- EM-7.6 "Facility Walkthroughs"
- Previously established guidance documentation used for DSA/TSR Implementation Verification Process (2003; Safety Basis Review Team).

3.0 REFERENCES AND DEFINITIONS

3.1 References

- 3.1.1 DOE P 450.5 *Line Environment, Safety and Health Oversight*
- 3.1.2 DOE O 413.1A, *Management Control Program*
- 3.1.3 DOE O 414.1A, *Quality Assurance*
DOE O 425.1C Startup and Restart of Nuclear Facilities
ORO O 410, Quality Assurance
- 3.1.6 ORO O 450, *Oak Ridge Operations Assessment Program*
- 3.1.7 EM Procedure EM-2.1, *Startup and Restart of Oak Ridge Reservation Environmental Management Program Work*

3.2 Definitions

Assessment: A formally planned and documented evaluation of activities, operations, and/or management systems to determine adherence with documented requirements and expectations as well as evaluate implementation effectiveness.

Causal Factors: The categorical underlying reason for the occurrence of an issue that, if corrected, prevents its recurrence. The causal factor categories will be identified and selectable within the ORION2 program.

Checklist: List of specific expectations and/or requirements developed from performance criteria that may be used by the assessor to evaluate and document the adequacy of a particular area being assessed.

Corrective Actions: Measures taken to correct the direct, contributing, and/or root causes of findings and observations such that the finding and observation will no longer exist or recur.

Documented Criteria: The contractual, regulatory, policy, order, procedure, or official memorandum mandating in writing the required action that must be taken by the assessed party to comply with a written requirement.

Findings: Non-conformances with contractual or regulatory requirements identified during an assessment. Findings are categorized either as Priority I, or Priority II, depending on the significance of the nonconformance. A Corrective Action Plan (CAP) is required for each Priority I & II finding. The finding priorities are defined as:

- [1] Priority I – These are findings of major significance that generally result in work cessation or work limitation. Such findings may include imminent threats to worker protection, public safety, and/or environmental quality. These findings can also include a systematic breakdown in, or a failure to implement a major work control element necessary for safety and quality.
- [2] Priority II – These findings represent non-conformances, deviations, and/or deficiencies in the implementation of requirements, procedures, standards, and/or regulations.

- 3.2.7 **Observation:** A condition that is considered negative and represents a potential problem and/or situation that if not corrected could lead to a finding. Example: An observation can be a minor noncompliance with a procedure that is not also a contractual or regulatory noncompliance. Multiple observations inside the same topical subject may constitute a finding and should be carefully reviewed prior to making a determination.
- 3.2.8 **Assessment/Walkthrough Lead:** An individual given the responsibility to assemble materials, direct activities, write reports, interface with the contractor, enter findings into ORION2, and verify CAP closure.
- 3.2.9 **Lines-of-Inquiry:** Specific expectations developed from the documented criteria that will be used by the assessor to evaluate the adequacy of a particular area they are assessing.
- 3.2.10 **ORION2:** The Oak Ridge Issues, Open Items, and Nonconformance Tracking System.
- 3.2.11 **Proficiencies:** A positive observation that highlights good practices, well-written procedures, or other positive aspects of a program that could be used as a model for other similar programs.
- 3.2.12 **Active Safety Systems (formerly known as Vital Safety Systems):** Those systems that have been credited in the DSA documents as controls that perform important roles to protect the health and safety of the public, workers and the environment. The following are examples:
- Confinement ventilation systems
 - Active portions of fire protection systems
 - Glovebox systems
 - Criticality monitoring systems
 - Radiation monitoring systems
 - Continuous air monitoring systems
- 3.2.13 **Verification/Validation:** An activity performed by the lead auditor/assessor when reviewing evidence to confirm that a corrective action has been implemented as required and that the corrective action has been effective in resolving the problem for which it was intended to address (Priority I and II findings only).

- 3.2.14 Walkthrough: The act of physically observing a contractor activity to verify that safe working conditions exist and applicable requirements are being followed during work implementation.

4.0 ROLES AND RESPONSIBILITIES

4.1 Assistant Manager for Environmental Management (AMEM)

Ensure that a walkthrough and assessment program is established and implemented.

- 4.2 Ensure that a prioritized and integrated schedule of assessments is implemented in accordance with requirements of this procedure.

Ensure that a corrective action management program is in place, in accordance with the requirements of this procedure, for timely and effective resolution of issues noted during assessment activities.

- 4.1.4 Approves the Integrated Assessment Schedule.

Monitors the conduct of the Integrated Assessment Program to ensure compliance with this procedure.

4.2 Contracting Officer's Representative

Approves and transmits all necessary direction to the contractor regarding actions expected of the contractor to address and remedy the findings and observations from walkthroughs and assessments of EM contractors.

Provides direction to the contractor on how they are to interact with ORO EM and external organizations with respect to corrective actions resulting from oversight activities within the scope of this procedure.

4.3 Division Directors

Provide input to the Technical Support and Assessment Division Director in the development and maintenance of the Integrated Assessment Schedule.

Distribute the Integrated Assessment Schedule to staff.

- 4.3.3 Ensure participating personnel comply with the Integrated Assessment Schedule.

- 4.3.4 Monitor the conduct of the Integrated Assessment Program.

Communicate recommended revisions and issues with the Integrated Assessment Schedule to the Technical Support and Assessment Division Director.

Participate in at least one assessment and/or walkthrough per quarter.

4.4 Technical Support and Assessment Division Director

Acts as the AMEM's assessment program manager and enforcement agent.

Establishes oversight program to monitor contractor activities, operations, and/or management systems.

- 4.4.3 Manages and maintains the Integrated Assessment Schedule.

- 4.4.4 Through the Project Manager ensures all applicable ORO EM personnel are trained to the requirements of this procedure.

Prepares revisions to the Integrated Assessment Schedule.

- 4.4.6 Monitors the conduct of the Integrated Assessment Program.

- 4.4.7 Participates in at least one assessment and/or walkthrough per quarter.

Ensures monthly summary status reports of overdue EM contractor corrective actions are provided to EM management.

4.5 Project Manager

Give input to the Technical Support and Assessment Division Director, through their respective Division Director, on the development and review of the Integrated Assessment Schedule.

Monitor the results of assessments and/or walkthroughs for their facilities.

Reviews, approves, and/or rejects contractor Response Reports and CAPs after considering line, SME, and other technical support input.

Ensures CAPs and/or corrective actions for walkthroughs and assessments are entered into ORION2.

Monitor the closure of corrective actions to ensure they meet the CAP, closed in a timely manner and are effective.

Verifies/validates the closure of contractor corrective actions in accordance with Corrective Action Plans.

Ensures changes to CAPs and/or corrective actions are approved at the same level as the original, are controlled and tracked until closure, and that closure basis is documented.

Participate in at least one assessment and/or walkthrough per quarter.

4.6 Team Leads

Provide the SME support necessary to develop and execute the Integrated Assessment Schedule.

Ensure walkthrough schedules are developed for their team's scope of work.

Ensure the Integrated Assessment Schedule contain the necessary scope to cover the appropriate programmatic and functional area topics at a sufficient frequency.

Approve changes to the walkthrough schedules.

In conjunction with the Project Manager, ensures ORION2 is utilized for documenting walkthroughs, assessments, corrective action plans, and corrective action completion. This includes approved changes and edits.

- 4.6.6 Ensure the walkthrough and assessment corrective actions are formally reported and routed through their respective Project Managers, then to the Contracting Officer's Representative before being sent to the contractor for resolution.

- 4.6.7 Communicate to subordinate personnel the Integrated Assessment Schedule.

- 4.6.8 Participate in at least one assessment and/or walkthrough per quarter.

Monitor the conduct of the Integrated Assessment Program.

4.7 Assessment/Walkthrough Lead

With support from the Division Directors, Project Managers, and Team Lead, select and schedule the personnel necessary to conduct the assessment/walkthrough.

Prepares guidance, adapts reference materials, and/or checklists to use during assessment/walkthroughs as appropriate.

- 4.7.3 Assembles and maintains assessment evidence files that are consistent with the scope of the assessment as appropriate. Evidence files are not required for walkthroughs.
- 4.7.4 Prepare walkthrough and assessment reports.
- 4.7.5 Reviews, comments, and/or concurs with contractor Response Reports and CAPs.
- 4.7.6 Assists with the verification of CAP closure when requested.

5.0 PROCEDURE

The following sections provide direction to all personnel who participate in the integrated assessment program.

5.1 Integrated Assessment Schedule

An Integrated Assessment Schedule is developed and maintained that includes ESH&Q and business project activities. Outline and populate it with the needed assessment topics taking into account input from the Division Directors and Project Managers. The following must be taken into consideration when developing the schedule.

- 5.1.1.1 The schedule should envelope a 36 month time frame based on a fiscal year format (October to September).
- 5.1.1.2 The schedule shall focus on the next 12 months.
- 5.1.1.3 The schedule shall have an approval signature(s) and a revision indicator.

Route the completed schedule to the Division Directors and Project Managers for their review of assessment topics and resource loading.

Make changes as appropriate to address comments and route to the Assistant Manager for Environmental Management for approval.

- 5.1.3.1 Send copies of the schedule to staff and field personnel as applicable.
- 5.1.4 The schedule shall be reviewed and updated quarterly to document the completion of assessment topics and/or edit the assessment schedule and reallocate resources based on changing requirements and needs.

The revised schedule must reflect a change in revision and be approved prior to being reissued.

5.2 Walkthroughs of Contractor Operations (Attachment "A" Parts I and II)

- 5.2. Walkthroughs may be scheduled or performed at a moments notice to cover planned and emergent topics. Formal guidelines or lines of inquiry should be developed prior to performing the walkthrough but are not mandated. At a minimum the Walkthrough Lead should have a topic or focus area and should have knowledge of the reference driving the topic or focus area.

A walkthrough schedule should be developed at the Division Director and Team Lead level. When developing the walkthrough schedule the following shall be considered:

- 5.2.2.1 The schedule should envelope a 12 month time frame.
- 5.2.2.2 The schedule should focus on the immediate 3 month window for completion.
- 5.2.2.3 The schedule should have an approval signature(s) and a revision indicator.

Copies of the schedule should be distributed to EM Management and the applicable contractor points of contact as appropriate.

The Walkthrough Lead shall coordinate and schedule SME and technical support as needed to complete the scheduled or emergent walkthrough topic.

The Walkthrough Lead shall conduct the walkthrough in accordance with this procedure.

- 5.2.5.1 For safety reasons, the walkthrough performer shall notify the appropriate Facility Manager, Safety Advocate, Subcontractor Technical Representative or other job site representative knowledgeable of safety and health requirements of a walkthrough activity. For accountability purposes the walkthrough performer shall sign in at the appropriate sign in location prior to entering the job site.
- 5.2.5.2 Any findings or observations noted during the walkthrough shall be shared with the Facility Representative.
- 5.2.5.3 During the assessment, if any activities are noted that represent an imminent threat to worker safety or environmental protection, the assessor will alert the participants of the assessed activity to Stop Work. The assessor will then immediately notify DOE Management following the appropriate chain-of-command.

Upon completion of the walkthrough, the Walkthrough Lead shall communicate the results to the appropriate Facility Manager, Project Manager, and Division Director.

A cover letter shall be drafted by the Walkthrough Lead for COR transmittal if there are any Priority 1 or 2 findings to communicate to the contractor. The formal cover letter shall include a request for a formal Response Report and Corrective Action Plan to include the following at a minimum:

- A determination of the extent of the deficiency.
- A corrective action schedule with specific activities as appropriate and the individual responsible.
- Immediate or interim corrective actions if resolution is long term.
- Direct and contributing causes.
- Root causes if the issue is considered systematic
- Direction to provide a CAP within two weeks from the date of the letter. This should be considered a goal and not a mandate.

After approval signatures are obtained from the COR, the ORION2 report and cover memo shall be forwarded to the contractor for disposition.

The Walkthrough Lead shall document the walkthrough, subsequent findings, observations and/or proficiencies into ORION2.

- 5.2.9.1 The Walkthrough Lead has a maximum of 1 - 2 weeks to enter the results into ORION2.

- 5.2.10 When a response report is received by the COR from the Contractor it shall be evaluated by the Project Manager and Walkthrough Lead for comment and/or approval.

- 5.2.10.1 The Walkthrough Lead will review the Response Report and CAP to ensure proper closure for the identified findings and comment as needed and forward the Response Report to applicable Division Directors and Project Managers for review and Comment.
- 5.2.10.2 The Project Manager shall review the Response Report and comment as needed. Review comments shall also be assembled from the Division Director for comment resolution.
- 5.2.10.3 The Project Manager shall coordinate the resolution of any comments with the contractor. The Walkthrough Lead should assist with the comment resolution as requested.
- 5.2.11 When comments to the Response Report and the CAP have been resolved the Project Manager shall ensure the CAP is entered into ORION2.
 - 5.2.11.1 The contractor's CAP tracking ID from their tracking database can be referenced in ORION2 instead of repeating the CAP description.
 - 5.2.11.2 If the contractor does not have a tracking database then the CAP must be repeated in ORION2 from the hard copy report.
- 5.2.12 The Project Manager shall ensure the CAPs are tracked to closure and closed out in ORION2 when they are completed.
 - 5.2.12.1 This can be accomplished via verbal and/or hard copy reports made to the Project Manager by the contractor informing them a finding has been closed.
- 5.2.13 If the contractor requires an extension to the CAP date or description, the Project Manager shall review and approve the revision.
 - 5.2.13.1 ORION2 shall be updated as needed to address the approved changes requested by the contractor.
 - 5.2.13.2 Revisions to the CAP shall be reported to management.

5.3 Formal EM Assessments of Contractor Operations (Attachment "B" Parts I and II)

- 5.3 Formal assessments require greater planning than walkthroughs. The planning will encompass the schedule, guidelines for conduct, and report writing. EM ORO assessments may include the following subject areas:

- Assessments and Corrective Actions of Contractor Operations (in accordance with DOE O 425.1C and EM Procedure 2.1)
- Safety Basis Changes and Implementation Verification
- Adequacy of contractor's Implementation Verification
- Assessment of Safety Significant Systems
- Project Management and Business Systems

5.3.1.1 Safety basis changes and implementation verification (including contractor's implementation verification) may be accomplished as part of the formal assessment process of the Operational Readiness Review or Readiness Assessment.

- 5.3.2 The Assessment Lead shall coordinate and schedule the SME and technical support required to make-up the assessment team and conduct the assessment.

.3.2 For Safety basis change and Implementation Verification Reviews (IVRs), the

cognizant facility representative and project manager should be included on the review team.

- 5.3.3 Assessments shall be of sufficient scope, duration, and frequency to ensure that ORO EM contractor operations are accomplished in a safe manner and within cost, schedule, and scope.
- 5.3.4 The organization to be assessed should be formally notified by the Assessment Lead at least two weeks in advance of the assessment.
- 5.3.5 Assessments shall be performed according to an assessment plan that is prepared by the Assessment Lead in advance of the assessment.
- 5.3.6 The assessment plan should contain the following:
 - 5.3.6.1 Objective: a brief statement of what the assessment is to accomplish.
 - 5.3.6.2 Scope: a brief summary of the topical areas that will be covered during the assessment, and the depth to which each will be covered.
 - 5.3.6.3 Assessment Methods: a listing of the planned date(s) of the assessment, team members, areas of review for each team member, general assessment techniques, and methods for issues communication during the conduct of the assessment.
 - 5.3.6.4 Listing of Performance Criteria References: applicable requirements, regulations, DOE Orders, procedures, and/or industry standards. For safety basis change and implementation verification reviews, the contractor's Implementation Plan shall serve as the basis for the validation criteria. DOE may include additional requirements if not adequately addressed by the contractor's Implementation Plan.
 - 5.3.6.5 Listing of Lines-of-Inquiry (See Definitions)
 - 5.3.6.5 Reporting Methods: a brief summary discussing the format of the assessment report and when draft and final reports will be released.
- 5.3.7 The assessment plan shall be submitted by the Assessment Lead to the organization to be assessed prior to the assessment beginning.
- 5.3.8 An in-brief will be held with the organization being assessed at the start of each assessment.
 - 5.3.8.1 The Assessment Lead shall conduct the in-brief and cover the scope of the assessment plan.
- 5.3.9 Assessment team staff must document the results of the assessment lines-of-inquiry using a checklist, a logbook, or similar. All documentation will be of sufficient detail to reconstruct the activity being observed as well as the inspection logic.
- 5.3.10 During the assessment, if any activities are noted that represent an imminent threat to worker safety, or environmental protection, the assessor will alert the participants of the assessed activity to Stop Work. The assessor will then immediately notify the affiliated DOE and contractor program managers and the DOE Facility Representatives.
- 5.3.11 For assessments that last more than one day, the opportunity for routine feedback meetings should be offered to the assessed organization by the Assessment Lead. At these meetings, the Assessment Lead should provide a status on the conduct of the assessment as well as any findings, observations, and proficiencies that have been identified.
- 5.3.12 Upon completion of the assessment, an out-brief shall be held with the assessed organization. At this meeting, a summary of the assessment results will be presented by the Assessment Lead. The time frame for delivery of the assessment report will also be discussed during this meeting.

- 5.3.12.1 Appropriate DOE and contractor personnel shall be invited to the closeout meeting (e.g. Division Director, Project Lead, Facility Representative, Contractor Facility Manager, etc.).
- 5.3.13 All assessments require a formal report. The report is prepared by the Assessment Lead with input from the team staff.
- 5.3.14 The content of the report shall include:
 - 5.3.14.1 Audit objective
 - 5.3.14.2 Scope covered during the assessment
 - 5.3.14.3 Methods of performance
 - 5.3.14.4 Results, including proficiencies, findings, and observations.
 - 5.3.14.5 For safety basis change and implementation verification reviews, the report shall include a conclusion on the adequacy of the contractor's Implementation Verification Review and the recommendation to approve operation under revised safety basis document or list of prerequisites and closure criteria..
- 5.3.15 A courtesy copy of the report shall be transmitted to the contractor Facility Manager.
- 5.3.16 A cover letter shall be drafted by the Assessment Lead for COR transmittal if there are any Priority 1 or 2 findings to communicate to the contractor. The formal cover letter shall include a request for a formal Response Report and Corrective Action Plan to include the following at a minimum:
 - A determination of the extent of the deficiency.
 - A corrective action schedule with specific activities as appropriate and the individual responsible.
 - Immediate or interim corrective actions if resolution is long term.
 - Direct and contributing causes.
 - Root causes if the issue is considered systematic
 - Direction to provide a CAP within two weeks from the date of the letter. This should be considered a goal and not a mandate.
- 5.3.16 As a general rule, the Assessment Lead should submit the official assessment report to the contractor, Division Directors, and Project Managers within 2 to 3 weeks of the assessment closeout meeting and enter issues into ORION2.
 - 5.3.16.1 Any corrective actions that were taken during the assessment and are listed in the assessment report must also be entered in ORION2.
- 5.3.17 After approval signatures are obtained from the COR, the ORION2 report and cover memo shall be forwarded to the contractor for disposition.
- 5.3.18 When a response report is received by the COR from the Contractor it shall be evaluated by the Project Manager and Assessment Lead for comment and/or approval.
 - 5.3.18.1 The Assessment Lead will review the Response Report and CAP to ensure proper closure for the identified findings and comment as needed and forward the Response Report to applicable Division Directors and Project Managers for review and Comment.
 - 5.3.18.2 The Project Manager shall review the Response Report and comment as needed. Review comments shall also be assembled from the Division Director for comment resolution.
 - 5.3.18.3 The Project Manager shall coordinate the resolution of any comments with the

contractor. The Assessment Lead should assist with the comment resolution as requested.

5.3.19 When comments to the Response Report and the CAP have been resolved the Project Manager shall ensure the CAP is entered into ORION2.

5.3.19.1 The contractor's CAP tracking ID from their tracking database can be referenced in ORION2 instead of repeating the CAP description.

5.3.19.2 If the contractor does not have a tracking database then the CAP must be repeated in ORION2 from the hard copy report.

5.3.20 The Project Manager shall ensure the CAPs are tracked to closure and closed out in ORION2 when they are completed.

5.3.20.1 This can be accomplished via verbal and/or hard copy reports made to the Project Manager by the contractor informing them a finding has been closed.

5.3.21 If the contractor requires an extension to the CAP date or description, the Project Manager shall review and approve the revision.

5.3.21.1 ORION2 shall be updated as needed to address the approved changes requested by the contractor.

5.3.21.2 Revisions to the CAP shall be reported to management.

5.4 Training, Qualification, and Experience Requirements

Personnel conducting walkthroughs and assessments shall be trained to the requirements of this procedure.

Lead Assessor/Auditor must have the personal attributes, skills, and experience to manage all phases of the assessment.

6.0 RECORDS

6.1 Program Records

6 Records generated as a result of implementation of this procedure include, but are not limited to:

1. Assessment Plans
2. Completed Lines-of-Inquiry or Checklists (as applicable)
3. Attendance Sheets
4. Audit Reports
5. Corrective Action Plan
6. Correspondence on changes to CAPs, including extensions and rejections
7. Letters requesting Corrective Action Plan
8. CAP approval letters
9. Evidence files for corrective action closure
10. Any other assessment correspondence

6. 2 Records shall be maintained in accordance with the established ORO EM Records Management System.

7.0 ATTACHMENTS

ATTACHMENT "A", Walkthrough Flow of Work and Responsibilities Part I, Walkthrough Preparation and Conduct

ATTACHMENT "A", Walkthrough Flow of Work and Responsibilities Part II, Response Report and CAP Disposition

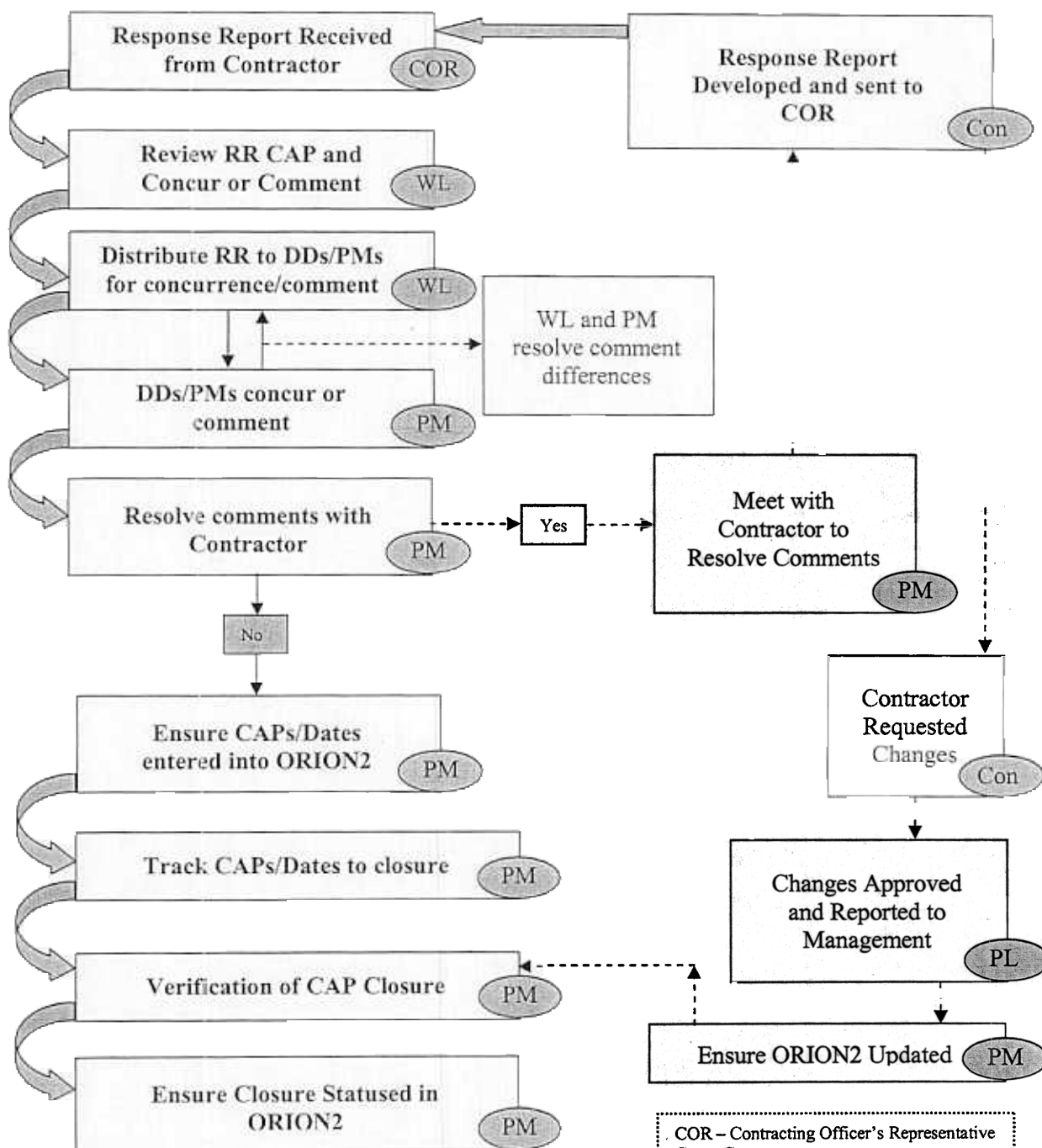
ATTACHMENT "B" Assessment Flow of Work and Responsibilities, Part I, Assessment Preparation and Conduct

ATTACHMENT "B", Assessment Flow of Work and Responsibilities, Part II, Response Report and CAP Disposition

ATTACHMENT "A"

Walkthrough Flow of Work and Responsibilities

Part II - Response Report and CAP Disposition

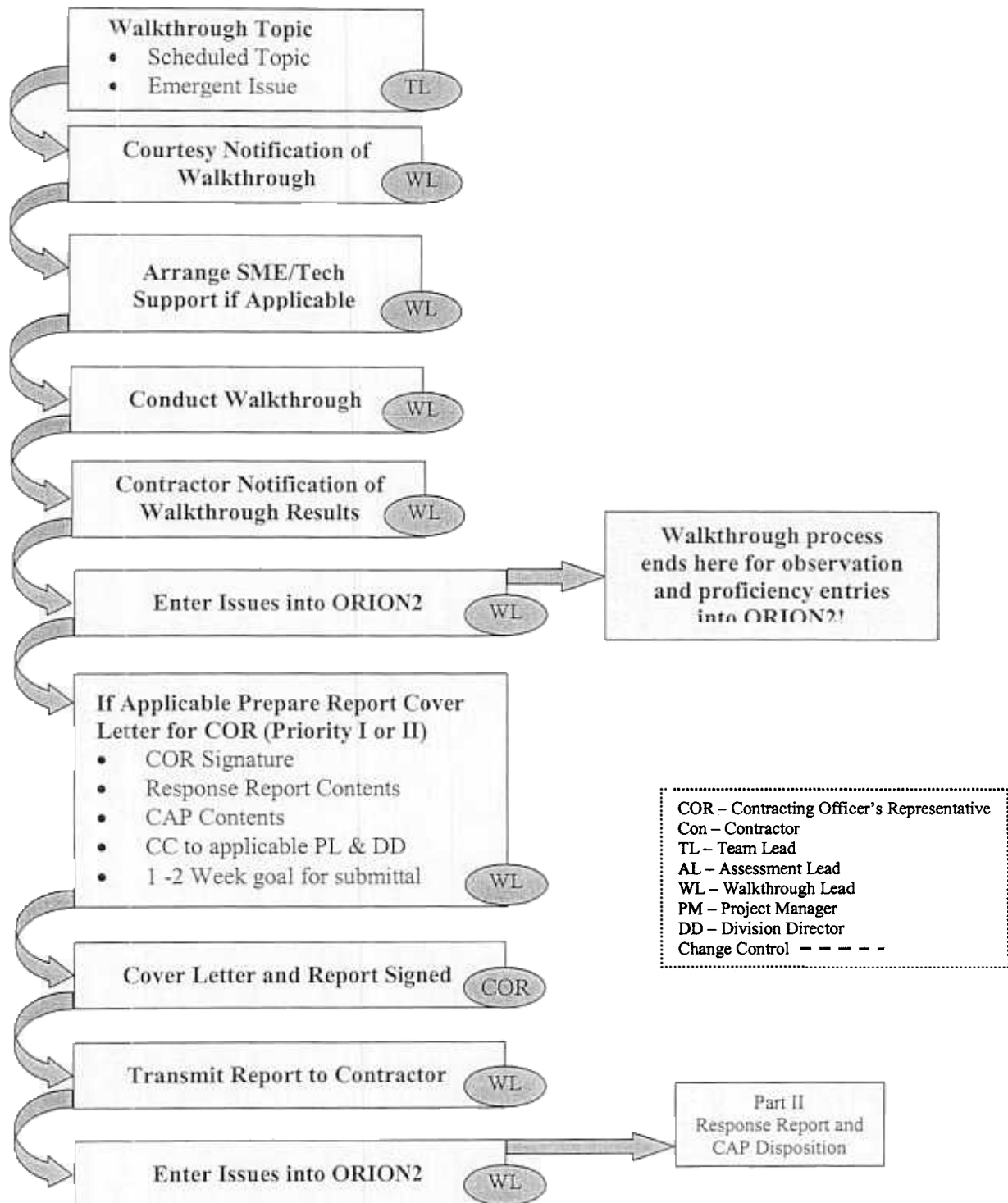


COR – Contracting Officer's Representative
Con – Contractor
TL – Team Lead
AL – Assessment Lead
WL – Walkthrough Lead
PM – Project Manager
DD – Division Director
Change Control - - - -

ATTACHMENT "A"

Walkthrough Flow of Work and Responsibilities

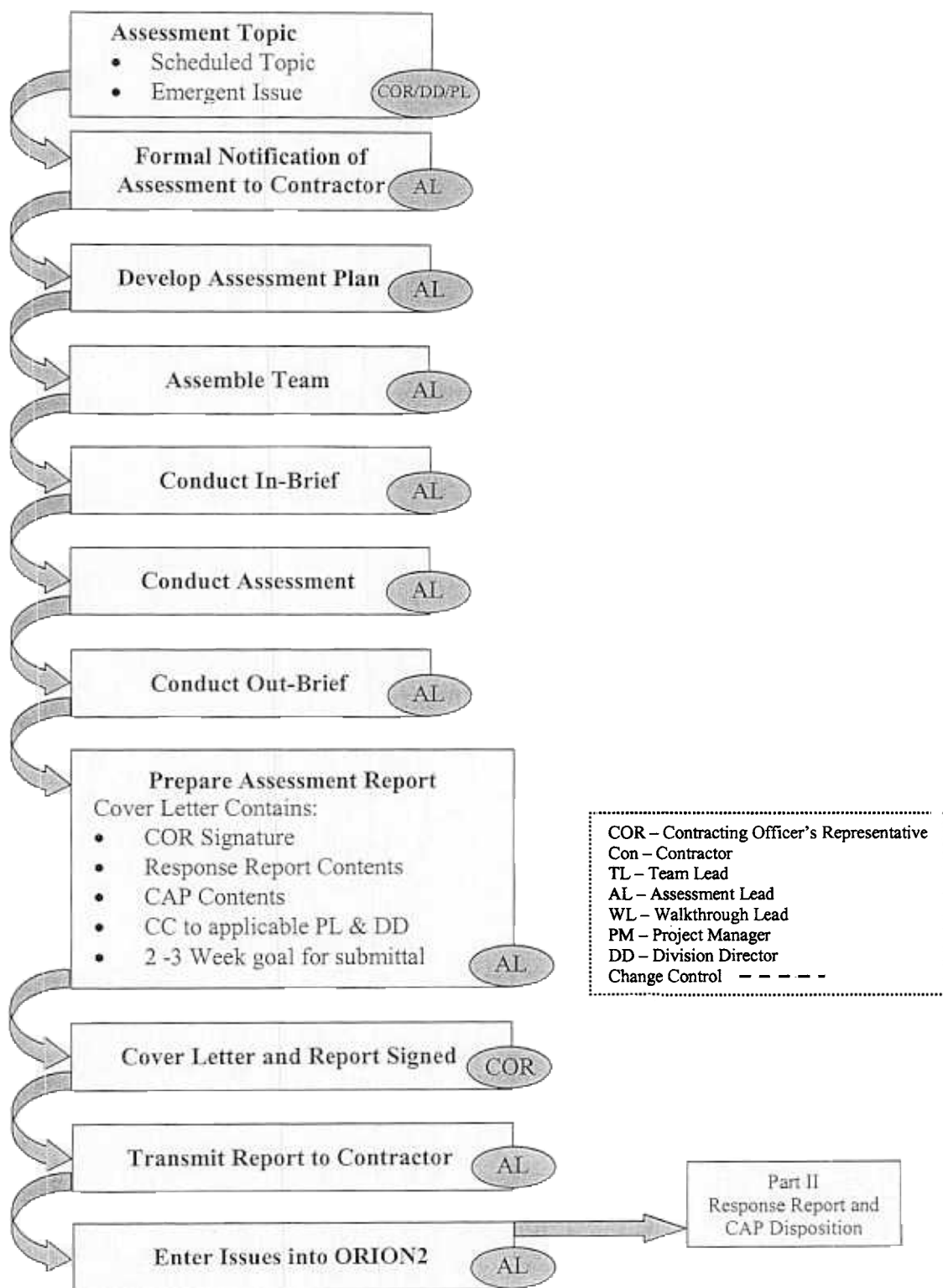
Part I - Walkthrough Preparation and Conduct



ATTACHMENT "B"

Assessment Flow of Work and Responsibilities

Part I - Assessment Preparation and Conduct



Part II - Response Report and CAP Disposition

